EXHIBIT D

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	**D. Christenson**	OMHA Appeal No.:	**1-8416270832** **1-8416229632**
Beneficiary:	**D. Christenson**	**Medicare Part B**	
Medicare No.:	*******3639A**	Before:	**Richard J. Zettel** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for the Appellant, D. Christenson.

Procedural History

The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") on a monthly basis from May 3, 2018, through October 3, 2018 (Exhibit 2). *See*, Attachment A. The Provider of the TTFT was Novocure Inc. Claims for the TTFT were submitted to a Part B Durable Medical Equipment Medicare Administrative Contractor (DME MAC), which were denied initially and upon redetermination (Exhibit 1). On March 12, 2019, and March 19, 2019, a Qualified Independent Contractor (QIC), C2C Solutions, Inc., issued unfavorable reconsideration decisions (Exhibit 1, page 1). The QIC determined that LCD L34823 details that TTFT will be denied as not reasonable and necessary. The QIC held the Provider liable for the non-covered charges.

On March 29, 2019, the Appellant submitted timely requests for an Administrative Law Judge (ALJ) hearing to the Office of Medicare Hearings and Appeals (OMHA) (Exhibit 3, pages 5 and 1). On April 19, 2019, the Provider submitted a request for an ALJ hearing to the OMHA (Exhibit 3, pages 1 and 14). The amount in controversy meets the jurisdictional requirement for a hearing before OMHA in each appeal (Exhibit 1).

A telephonic hearing before the ALJ was held on May 15, 2019, in Cleveland, Ohio. Debra Parrish, Esq. appeared on behalf of the Appellant. Julie Miles, RN, Clinical Appeals Specialist,

appeared on behalf of the Appellant and testified under oath. Exhibits 1-4 were admitted into the record in each appeal.

Issues

The ALJ is asked to decide whether the TTFT provided to the Appellant on multiple dates of service is reimbursable under Part B of Title XVIII of the Social Security Act, and if not, who is liable for the non-covered charges.

Findings of Fact

The attached Exhibit List is incorporated into this Decision by reference. The following facts are established by the preponderance of the evidence.

1. The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") (also known as "Optune") on a monthly basis from May 3, 2018, through October 3, 2018 (Exhibit 2). *See*, Attachment A.

2. The Appellant was 63 years-old during the dates of service at issue (Exhibit 2, page 1).[1]

3. On July 20, 2015, the Appellant underwent a right parietal occipital craniectomy (Exhibit 2, page 48). The biopsies of the right occipital brain tumor showed high grade glial tumor consistent

4. The record of the appeal includes office notes documenting the Appellant's treatment for glioblastoma multiforme, including surgery, radiation, and chemotherapy (Exhibit 2).

5. The Appellant received primary therapy with temozolomide and external beam radiation therapy (*Id.* and Exhibit 2, page 6). He had recurrence in the surgical bed roughly four months later and was treated with radiosurgery.

6. In 2016, the Appellant began using Optune therapy. *Id.* Since that time through September 19, 2018, the Appellant had been stable, if not improved in his imaging.

7. On September 18, 2018, an MRI of the brain revealed the following: stable postoperative findings of right craniotomy for right occipital tumor resection with unchanged appearance of the heterogeneously enhancing resection cavity; no evidence of tumor progression; flair hyperintense signal surround the resection cavity and extending throughout the right cerebral hemisphere; and unchanged mass effect with 4 mm midline shift to the left (Exhibit 2, page 8).

8. The plan was for the Appellant to continue on Optune therapy indefinitely (Exhibit 2, page 6).

[1] Exhibit numbers refer to OMHA Appeal No. 1-8416229632 unless otherwise specified.

9. Page two of three of the Optune Prescription Form was signed by the Appellant on September 22, 2016 (Exhibit 2, page 3).

10. Page one of five of the Optune Prescription Form was signed by the physician on November 29, 2017 (Exhibit 2, page 2). The prescription provides that the Beneficiary had a diagnosis of glioblastoma multiforme. The prescription provides that it was a renewal.

11. Page one of five of the Optune Prescription Form was signed by the physician on May 16, 2018 (Exhibit 2, page 1). The prescription provides that the Beneficiary had a diagnosis of recurrent GBM (glioblastoma multiforme).

12. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors (Exhibit 4, page 7; Hearing testimony).

13. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. *Id.*

14. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTFT for their glioblastoma (Exhibit 1 (both appeals); Hearing testimony).

15. TTFT for glioblastoma is included in the National Comprehensive Cancer Network (NCCN) guidelines (Exhibit 1, page 46). The NCCN guidelines for recurrent glioblastoma include "consider alternate electric field therapy for glioblastoma (Category 2B)."

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A hearing before an ALJ is only available if the remaining amount in controversy is $160. 83 Fed. Reg. 47619 (Sept. 20, 2018) (setting the 2019 amount in controversy threshold amount at $160). The request for hearing is timely if filed within sixty days after receipt of the QIC's reconsideration decision. *See*, 42 C.F.R. § 405.1002.

B. Scope of Review

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing." *See*, 42 C.F.R. § 405.1032(a).

C. Standard of Review

Pursuant to § 557 of the Administrative Procedure Act ("APA"), an ALJ qualified and appointed pursuant to the APA acts as an independent finder of fact in conducting a hearing pursuant to § 1869 of the Act. The ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Social Security Act and Code of Federal Regulations

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program. For claims for durable medical equipment, prosthetics, orthotics, and supplies, DME MACs administer the processing of the claims.

Part B of Title XVIII of the Act, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Section 1862(a)(1) of the Act excludes Medicare payment for services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member".

Section 1834(a)(15)(C) of the Act provides that carriers shall, at the request of a supplier or beneficiary, determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered if the item is a customized item, the patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and the item is not an inexpensive item as specified by the Secretary.

Section 1832(a) of the Act states, in pertinent part: The benefits provided to an individual by the insurance program established by this part shall consist of

> (1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical or other health services…

Section 1861(s) of the Act provides that the term "medical and other health services" includes durable medical equipment. 42 CFR § 414.202 defines durable medical equipment as equipment furnished by a supplier or a home health agency that-

(1) can withstand repeated use;

(2) is primarily and customarily used to serve a medical purpose;

(3) generally is not useful to an individual in the absence of an illness or injury; and

(4) is appropriate for use in the home.

42 CFR § 410.38(a) provides in pertinent part as follows regarding the scope and conditions of durable medical equipment:

> Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

B. CMS Manual System and Local Policy

The manuals issued by the Centers for Medicare and Medicaid Services (CMS) administering the Medicare program also are considered. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it. CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 15, § 110, provides general coverage guidelines for durable medical equipment.

CMS, *Medicare Program Integrity Manual (MPIM)(Internet-Only Manual Publ'n 100-8)* ch. 13, § 13.5.1 includes the follow guidance for contractors when drafting a proposed Local Coverage Determination (LCD):

> In order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
> • Safe and effective;
> • Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
> • Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
> o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

o Furnished in a setting appropriate to the patient's medical needs and condition;
o Ordered and furnished by qualified personnel;
o One that meets, but does not exceed, the patient's medical need; and
o At least as beneficial as an existing and available medically appropriate alternative.

MPIM, supra ch. 13, § 13.7.1 continues as follows:

> In order of preference, LCDs should be based on:
> • Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
> • General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
> o Scientific data or research studies published in peer-reviewed medical journals;
> o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
> o Medical opinion derived from consultations with medical associations or other health care experts.
> Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

A Local Coverage Determination (LCD), as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with § 1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary). CGS Administrators and Noridian Healthcare Solutions, LLC issued Local Coverage Determination: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017), which provides in relevant part as follows: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The QIC determined that LCD L34823 details that TTFT will be denied as not reasonable and necessary. The QIC held the Provider liable for the non-covered charges. The Appellant argues that TTFT should be covered by Medicare. The ALJ disagrees with the findings of the QIC and determines that the TTFT provided to the Appellant is covered under Part B of Medicare.

Medicare is a defined benefit program, which means that it does not cover all available medical services and supplies. Medicare coverage is limited to those medical services and supplies identified by Congress, and by the Secretary of Health and Human Services and CMS in implementing Congressional directives. Medicare does not cover medical services that are not medically reasonable and necessary under § 1862(a)(1) of Act.

The QIC relied upon LCD L34823 to deny coverage for the TTFT for the Appellant. LCD L34823 provides that TTFT will be denied as not reasonable and necessary. Pursuant to 42 C.F.R. § 405.1062(a), an ALJ must give substantial deference to local coverage determinations. If an ALJ declines to follow a local coverage determination, the ALJ must explain the reason

why the policy was not followed in accordance with 42 C.F.R. § 405.1062(b). After careful consideration of the record and hearing testimony, the ALJ has decided to depart from LCD L34823 under the specific facts of this appeal.

First, the ALJ finds that LCD L34823 fails to identify any justification for the denial of all TTFT as not reasonable and necessary. Pursuant to *MPIM supra* ch. 13, §13.7.1, contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is safe and effective. The record and hearing testimony support that TTFT is a safe and effective treatment of glioblastoma. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network guidelines. The NCCN guidelines for recurrent glioblastoma include "consider alternate electric field therapy for glioblastoma (Category 2B)." The Appellant pointed out that many payers are covering TTFT based on individual medical necessity review as a well as published medical policy. *See*, Exhibits 1. Therefore, the ALJ will not afford substantial deference to LCD L34823 and concludes that TTFT is a safe and effective treatment of recurrent glioblastoma.

Second, the ALJ finds that the documentation and hearing testimony support that TTFT is medically reasonable and necessary to treat the Appellant. The Appellant was 63 years-old during the dates of service at issue. On July 20, 2015, the Appellant underwent a right parietal occipital craniectomy. The biopsies of the right occipital brain tumor showed high grade glial tumor consistent. The record of the appeal includes office notes documenting the Appellant's treatment for glioblastoma multiforme, including surgery, radiation, and chemotherapy. The Appellant received primary therapy with temozolomide and external beam radiation therapy. He had recurrence in the surgical bed roughly four months later and was treated with radiosurgery.

In 2016, the Appellant began using Optune therapy. Since that time through September 19, 2018, the Appellant had been stable, if not improved in his imaging. On September 18, 2018, an MRI of the brain revealed the following: stable postoperative findings of right craniotomy for right occipital tumor resection with unchanged appearance of the heterogeneously enhancing resection cavity; no evidence of tumor progression; flair hyperintense signal surround the resection cavity and extending throughout the right cerebral hemisphere; and unchanged mass effect with 4 mm midline shift to the left. The plan was for the Appellant to continue on Optune therapy indefinitely. Ms. Miles stated that the Appellant was diagnose with brain cancer in July 2015 and was put on Optune. Ms. Miles said that the Appellant was still alive, which is phenomenal. Ms. Miles noted that the Appellant's compliance with therapy is excellent.

Based on the foregoing, the TTFT provided to the Appellant on the dates of service was medically reasonable and necessary. The TTFT provided to the Appellant from May 3, 2018, through October 3, 2018, is reimbursable under Part B of Medicare.

Conclusions of Law

The ALJ concludes that the TTFT provided to the Appellant on multiple dates of service was medically reasonable and necessary. Accordingly, the ALJ finds that the TTFT provided to the

Appellant from May 3, 2018, through October 3, 2018, is reimbursable under Part B of Title XVIII of the Act. *See*, Attachment A.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: June 6, 2019

SO ORDERED,

Richard J. Zettel
U.S. Administrative Law Judge

Enclosures:

Form OMHA-156, *List of Exhibits*